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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,517	06/30/2006	James R. Howard		8067

76809 7590 05/20/2009

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
05/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,517	HOWARD, JAMES R.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt of applicant's arguments/Remarks and amended claims filed on 02/23/09 are acknowledged.

Claims 1 and 18 have been amended. Claims **1-18** are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over teachings of Howard (US 5,973,004) in view of Hamilton (US 6,479,069 B1).

Howard teaches a composition containing L-carnitine, acetyl-L-carnitine, pantothenic acid or ubiquinone for treating ineffective energy metabolism (Title).

Howard also teaches that both pantothenic acid and ubiquinone can also be used in combination with L-carnitine and, acetyl-L-carnitine (Col.18, claim 15, lines 5-7).

Howard's composition contains L-carnitine, acetyl-L-carnitine, pantothenic acid and ubiquinone and is administered orally or as a parenteral injection in animals and humans for prevention or treatment of syndromes or diseases arising from dysfunctional energy metabolism (Abstract). Their ratio in mg is at 0.5, 0.5, 0.1 and 0.1 per pound of the body weight of the domesticated mammal or human being treated (Col.17, Claim 2 lines 2-5) which is in the ratio of 1: 1: 0.2 : 0.2 and is with in the range as claimed by applicant (Claim 2). Howard's pharmacological composition contains preservative (Col. 18, claim 8, line 2) and the aqueous solution of the preparation can be administered orally (Claim 16) at a concentration that is pharmacologically effective for treating dysfunctional energy metabolism conditions (Claim 10). Howard teaches use of his preparation as mixed with food or drink or consumed directly (Col.17, lines 10-12), thus suggesting that it can be taken in a concentrate and in a soft drink. Howard teachings include use of the composition in the form of a gelatin capsule (Col. 18, claim 12). Howard teachings include use of the pharmacological preparation for treating dysfunctional energy metabolism comprising cardiomyopathy, epilepsy (Col.17, claim 1, lines 1-5) and seizures (Col.13, lines 62-64).

Howard's teachings lack use of Niacin. Hamilton teaches nutritional supplement for increased energy and stamina containing L-carnitine and effective amounts of coenzyme Q which is ubiquinone (Abstract). Hamilton's supplement also contains

niacin, pantothenic acid (Col. 9, example1, lines 50 and 54), and acetyl-L-carnitine (Col.12, claim 1b).

One of ordinary skill in the art would be motivated to add niacin in Howard's composition as taught by Hamilton, as Hamilton also teaches an energy supplement comprising niacin. One of ordinary skill would expect an additive effect by addition of niacin in Howard's composition. Additionally it would be obvious to one of ordinary skill in the art to arrive at an optimal concentration of niacin for the desired effect by optimizing the amounts. One of ordinary skill in the art would have a reasonable expectation of success by providing a composition comprising L-carnitine, acetyl-L-carnitine, pantothenic acid and niacin for the treatment of dysfunctional energy metabolism syndrome based on the teachings of the two references.

Response to Arguments

4. Applicant's arguments filed 02/23/09 have been fully considered but they are not persuasive.

Applicants contend that "neither reference nor the two taken together teach the use of L-carnitine, acetyl-L-camitine, pantothenate and niacinamide in partially closed method and composition claims that recite "consisting essentially of" to highlight the importance of the four-way components specifically. By means of the amendments filed herewith, therefore, the claims define over, and are nonobvious over, the prior art cited by the Examiner.

Applicant's arguments are not persuasive. As per MPEP:)

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

In the instant case there is nothing in the specification that affects the basic and novel characteristics of the invention. While it is true that neither of the references teach all the components claimed individually. However, Howard teaches a composition containing L-carnitine, acetyl-L-carnitine, pantothenic acid or ubiquinone for treating ineffective energy metabolism (Title). Howard also teaches that both pantothenic acid and ubiquinone can also be used in combination with L-carnitine and, acetyl-L-carnitine (Col.18, claim 15, lines 5-7). What is lacking in Howard is the presence of nicacin. Hamilton while teaching an energy supplement teaches utilizing niacin in the composition. As such one skill in the art would have been motivated to utilize niacin in the teachings of Howard and come to the claimed invention with a reasonable expectation of success since both the references are directed to the energy enhancement composition.

Applicant argues that the niacin in Hamilton is an incidental constituent of the boost starting material to which Hamilton adds further nutritional components where as in the instant invention the claimed components remediate the cardiovascular or indications and niacin prevents later development of pellagra. Applicant's arguments are not persuasive because the claims are drawn to a composition and the sequence how and when niacin is added is not material to the composition. additionally no such limitations have been recited in claims. Claims also do not recite that niacin eventually treats pellegra. In response to applicant's argument that the references fail to show

certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., niacin preventing pellegra are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)270-5263. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/
Examiner, Art Unit 1612
/Gollamudi S Kishore /
Primary Examiner, Art Unit 1612